



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

The Development and Evaluation of Human Cytomegalovirus Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration, Center for Biologics Evaluation and Research, the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, and the National Vaccine Program Office are announcing a public workshop entitled "The Development and Evaluation of Human Cytomegalovirus Vaccines." The purpose of the public workshop is to identify and discuss key issues related to the development and evaluation of human cytomegalovirus (HCMV) vaccines. The public workshop will include presentations on HCMV disease and pathogenesis and issues related to vaccine development.

Date and Time: The public workshop will be held on January 10 and January 11, 2012, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Pre-registered participants will receive additional information on parking and public transportation with their email registration confirmation.

Contact Person: Manen Bishop, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-

1448, 301-827-2000, FAX: 301-827-3079, email: CBERTraining@fda.hhs.gov (Subject line: HCMV Vaccine Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Manen Bishop (see Contact Person) or email to CBERTraining@fda.hhs.gov (Subject line: HCMV Workshop Registration) by December 12, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Manen Bishop (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

HCMV, also known as human herpesvirus 5, infects approximately half of the U.S. population by adulthood. While most infections are without symptoms, the infection is lifelong. However, the disease may become apparent in children who were infected during gestation (congenital HCMV) and in infected individuals with weakened immune systems. Congenital HCMV infection causes mental retardation, learning disabilities, hearing loss, vision loss, and other disabilities. Patients undergoing stem cell or solid-organ transplants are at particularly high risk for severe disease or death from HCMV infection.

An effective vaccine could have a significant impact on rates of congenital anomalies and severe infections caused by HCMV. However, efforts to develop a vaccine against HCMV have not yet been successful.

The public workshop will focus on the status of knowledge about HCMV biology and epidemiology and on vaccine development strategies. Topics for discussion will include: (1)

HCMV epidemiology and diagnosis, (2) HCMV immunology and virology, (3) manufacturers' and regulators' perspectives, (4) target populations for a HCMV vaccine, (5) design of clinical trials to study HCMV vaccines in the setting of congenital HCMV and transplants, and (6) next steps toward development of HCMV vaccines.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at:

<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in

writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: November 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.